



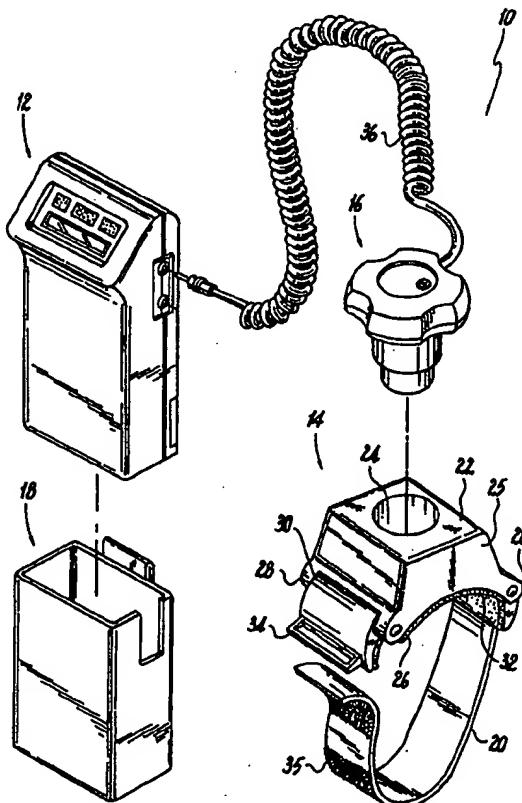
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(54) Title: METHOD AND APPARATUS FOR ULTRASONIC TREATMENT OF CARPAL TUNNEL SYNDROME

(57) Abstract

The invention relates to an apparatus and method for therapeutically treating carpal tunnel or hand/wrist injuries using ultrasound. The apparatus (10) includes at least one ergonomically constructed ultrasonic transducer configured to cooperate with a placement module or strip for placement in proximity to the carpal tunnel or hand/wrist injury. The apparatus (10) also utilizes a portable, ergonomically constructed main operating unit (12) constructed to fit within a pouch (18) worn by the patient. In operation, at least one ultrasonic transducer positioned adjacent the carpal tunnel or hand/wrist injury is excited for a predetermined period of time. To ensure that at least one ultrasonic transducer is properly positioned, and to insure compliance with a treatment protocol, a safety interlock (70) is provided to prevent inadvertent excitation.



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METHOD AND APPARATUS FOR ULTRASONIC TREATMENT OF CARPAL TUNNEL SYNDROME

PRIORITY

This application claims priority to a Provisional Application filed on October 9, 1997 by Talish et al. having U.S. Provisional Application No. 60/062,414, the contents of which are hereby incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 The present invention relates to a method and apparatus for therapeutically treating injuries using ultrasound. More particularly, the present invention relates to a method and apparatus which utilizes an ergonomically constructed ultrasonic transducer configured to cooperate with a placement module for placement in proximity to the wrist or hand for therapeutically treating carpal 10 tunnel syndrome.

2. Description of the Related Art

15 The use of ultrasound to therapeutically treat and evaluate bone injuries is known. Impinging ultrasonic pulses having appropriate parameters, e.g., frequency, pulse repetition, and amplitude, for suitable periods of time and at a proper external location adjacent to a bone injury has been determined to accelerate the natural healing of, for example, bone breaks and fractures.

U.S. Patent No. 4,530,360 to Duarte describes a basic non-invasive therapeutic technique and apparatus for applying ultrasonic pulses from an operative surface placed on the skin at a location adjacent a bone injury. The applicator 20 described in the Duarte patent has a plastic tube which serves a grip for the operator, an RF plug attached to the plastic tube for connection to an RF source, and internal cabling connected to an ultrasonic transducer. To apply the ultrasound pulses during treatment an operator must manually hold the applicator in place until

5 the treatment is complete. As a result, the patient is, in effect, immobilized during treatment. The longer the treatment period, the more the patient is inconvenienced. The Duarte patent also describes a range of RF signal for creating the ultrasound, ultrasound power density levels, a range of duration for each ultrasonic pulse, and a range of ultrasonic pulse frequencies.

10 U.S. Patent No. 5,003,965 to Talish et al. relates to an ultrasonic body treatment system having a body-applicator unit connected to a remote control unit by sheathed fiber optic lines. The signal controlling the duration of ultrasonic pulses and the pulse repetition frequency are generated apart from the body-applicator unit. Talish et al. also describes a mounting fixture for attaching the 15 body-applicator unit to a patient so that the operative surface is adjacent the skin location.

20 While the systems described in these patents relate to therapeutic methods and apparatus for ultrasonic treatment there is a need for ergonomically configured signal generators and transducers which permit patient mobility during the treatment of carpal tunnel syndrome or a variety of hand/wrist injuries and/or problems. Further, a need exists for an apparatus which optimizes the treatment of carpal tunnel syndrome or a variety of hand/wrist injuries while maintaining patient mobility.

25 Carpal tunnel syndrome is a condition that results from pressure on the median nerve where it passes into the hand via a gap (the "carpal tunnel") under a ligament at the front of the wrist. The median nerve carries sensory messages from the thumb and some fingers and also motor stimuli to the muscles in the hand; damage to the nerve causes sensory disturbances, particularly numbness or tingling, and weakness. Treatment typically entails resting the affected hand at night in a 30 splint. If symptoms persist, a small quantity of a corticosteroid drug may be

5 injected under the ligament in the wrist. If this fails to help, surgical cutting of the ligament may be performed to relieve the pressure on the nerve.

SUMMARY OF THE INVENTION

10 The ultrasonic treatment apparatus of the present invention is used for therapeutically treating carpal tunnel syndrome including hand/wrist injuries using ultrasound. The apparatus includes an ergonomically constructed placement module configured for mounting thereon at least one ultrasonic transducer assembly with an integral signal generator which provides excitation signals to ultrasonic transducers within the transducer assembly. Timing control circuitry as well as monitoring circuitry for the proper attachment and operation of the transducer 15 assembly are housed within a portable main operating unit constructed to fit within a pouch worn by the patient. In operation, the placement module is positioned on a patient's hand and/or wrist such that at least one transducer is positioned in proximity to the carpal tunnel or hand/wrist injury. At least one transducer is then excited for a predetermined period of time.

20 Preferably, the main operating unit has an internal power source for powering the signal generator circuitry, a display coupled to the signal generator circuitry to display treatment sequence data, a keypad coupled to the signal generator circuitry to permit user operation and/or entry of data. The signal generator circuitry includes a processor, means for generating a pulsed control 25 signal, and a switch coupled to the processor for regulating the pulsed control signal. A communication interface may be connected between a communication port and the processor to provide a communication link between the ultrasonic signal generator and an external computer or modem. Preferably, the communication interface is a serial communication interface, however, a parallel 30 interface is also contemplated. An alarm is provided to indicate to the user that the treatment time has expired. The alarm is coupled to the processor such that when

5 ultrasonic treatment is completed the processor activates the alarm and terminates ultrasound generation.

The present invention also provides a kit for ultrasonically treating carpal tunnel syndrome while maintaining patient mobility. The kit includes an ultrasonic transducer assembly, a placement module configured to be worn by a patient adjacent the carpal tunnel or hand/wrist injury and configured to receive the ultrasonic transducer assembly, an integrated ultrasonic signal generator located in the ultrasonic transducer assembly, a main operating unit (MOU) or controller and a pouch constructed to receive the MOU. Preferably, the MOU has an internal power source and is fitted within a pouch which is releasably secured to a patient during treatment thereby providing patient mobility. A MOU envisioned for use with the present invention is described in U.S. Patent No. 5,556,372 issued to Talish et al. on September 17, 1996, the contents of which are hereby incorporated by reference.

20 The MOU is electrically coupled to at least one transducer secured to the placement module. The signal generator corresponding to each transducer is then activated so as to excite the ultrasonic transducers for impinging ultrasonic waves against the carpal tunnel or hand/wrist injury.

25 A method for ultrasonically treating carpal tunnel syndrome including hand/wrist injuries while maintaining patient mobility is also provided. Once the location of the carpal tunnel or hand/wrist injury is ascertained, a placement module containing an ultrasonic transducer assembly having at least one transducer and one signal generator is affixed to the patient's hand and/or wrist such that at least one transducer is adjacent the carpal tunnel or hand/wrist injury.

30 In an alternative embodiment, a series of transducers are attached to a placement module and are controlled by a MOU. In another embodiment, a placement module is provided for securing a plurality of transducers thereto in a plurality of configurations.

5

Further, the present invention also provides a strip having at least one ultrasonic transducer secured thereto for placement along the hand directly above the carpal tunnel for the treatment of carpal tunnel syndrome.

BRIEF DESCRIPTION OF THE DRAWINGS

10

Preferred embodiments of the invention are described below with reference to the drawings, which are described as follows:

Fig. 1 is a perspective view with parts separated of a first embodiment of a portable ultrasonic treatment apparatus according to the present invention, illustrating a main operating unit or controller and a placement module;

15

Fig. 2 is a perspective view of a patient wearing the portable treatment apparatus of Fig. 1;

Fig. 3 is a cross-sectional view along line 3-3 in Fig. 2 illustrating the transducer assembly impinging ultrasonic waves to a patient's carpal tunnel, where a gel-like substance is positioned between the transducer assembly and the patient's wrist;

20

Fig. 4 is a perspective view of the transducer assembly impinging ultrasonic waves to a patient's carpal tunnel where an alternative embodiment for the placement module is used;

Fig. 5 is a block diagram of the circuitry for the ultrasonic transducer assembly;

25

Fig. 6 is a perspective view of a second embodiment of the portable ultrasonic treatment apparatus, illustrating a main operating unit or controller and a placement module having a series of transducers;

Fig. 7 is a perspective view of a patient wearing the portable treatment apparatus of Fig. 6;

30

Fig. 8 is a side view of a patient wearing the portable treatment apparatus of Fig. 6;

5 Fig. 9 is a perspective view of a patient wearing a portable treatment apparatus of a third embodiment configured for mounting a plurality of transducers in a plurality of configurations in proximity to the patient's hand and/or wrist;

Fig. 10 is a cross-sectional view along line 10-10 of Fig. 9;

10 Fig. 11 is a perspective view of a patient wearing a portable treatment apparatus of a fourth embodiment configured for treating carpal tunnel syndrome and hand/wrist injuries; and

Fig. 12 is a cross-sectional view along line 12-12 of Fig. 11.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The ultrasonic treatment apparatus of the present invention is used for the surgically non-invasive utilization of ultra high-frequency acoustic energy in the treatment of carpal tunnel syndrome including hand/wrist injuries, such as accelerating the healing of a wrist-fracture. The treatment of other musculoskeletal injuries including cranial and venous ulcers are also contemplated with the present invention. The apparatus includes an ergonomically constructed placement module having a strap or other fastening means for being secured to a patient's hand and/or wrist. At least one ultrasonic transducer assembly partially fabricated with a conductive plastic material is attached or imbedded within the placement module and properly positioned in proximity to the carpal tunnel or hand/wrist injury. Different types of ultrasonic transducers can be provided, such as those described and schematically depicted in U.S. Patent No. 5,520,612 issued to Winder et al. on May 28, 1996, the contents of which are hereby incorporated by reference. Particularly, the transducers and arrangements schematically depicted by Figs. 7-11 of the application in which at least one transducer is used to provide acoustic energy to the site of the injury. The apparatus also utilizes a portable, ergonomically constructed main operating unit (MOU) which is constructed to fit within a pouch worn by the patient using belt and shoulder strap and provides control signals to the ultrasonic transducers. The MOU which is utilized is preferably the one described

5 in U.S. Patent No. 5,556,372 issued to Talish et al. on September 17, 1996, the contents of which are hereby incorporated by reference.

10 Turning to the figures, in particular Fig. 1, one embodiment of the portable ultrasonic treatment apparatus 10 of the present invention is shown. The ultrasonic treatment apparatus 10 includes a MOU 12, a placement module 14, an ultrasonic transducer assembly 16, and a pouch 18 for releasably securing the MOU 12 to the patient during treatment for providing patient mobility. The placement module 14 is comprised of a placement band 20 and a placement support 22. The placement support 22 includes a pocket 24 adapted for placement of the ultrasonic transducer assembly 16 therein. The placement support 22 further includes a base 25, a wrist rest 26 and two lateral supports 28 each forming an opening 30 with respect to the base 25 for connecting the placement support 22 to the placement band 20. A sponge-like material 32 lines the inner surface of the placement support 22 for providing comfort to the patient. A fastener 34 is provided to the placement band 20 for strapping the placement module 14 to the patient's wrist. A portion of the placement band 20 is lined with VELCRO[™] material 35 to firmly secure the placement module 14 to the patient's wrist.

15 The transducer assembly 16 includes circuitry, schematically illustrated by Figs. 5 and 5A and described below, for exciting at least one transducer therein and is coupled to the MOU by cable 36. The cable 36 is preferably multiconductor cables capable of transmitting relatively low frequency RF or optical signals, as well as digital signals. The cable 36 may include coaxial cable or other types of suitable shielded cable. Alternatively, the cables 36 may 20 include fiber optic cable for transmitting optical signals. The signals may be transmitted continuously or as a series of pulses.

25 In operation, the placement module 14 is positioned and secured to the patient's wrist as shown by Figs. 2 to 4, such that the transducer assemblies 16 lie over the carpal tunnel 100 or hand/wrist injury. The carpal tunnel 100 contains the median nerve 102, nine flexor tendons 104 and their flexor sheaths and four

5 carpal bones, which includes the hamate 106, capitate 108, trapezoid 110, and trapezium 112 which are tightly bound together to form the dorsal, medial and lateral walls of the tunnel. A locating ring such as the one disclosed in U.S. Patent
10 No. 5,556,372 may be used for determining the location of injured bone in the case of a hand/wrist injury before the placement module 14 is secured to the patient's hand. Once the placement module 14 is properly positioned, the transducer within each transducer assembly is excited for a pre-determined amount of time to impinge ultrasonic waves towards the carpal tunnel 100. An alternative embodiment of the placement module 14 is shown by Fig. 4. A gel-like substance 37 may be
15 positioned between the transducer assembly 16 and the patient's wrist to prevent attenuation of the ultrasonic waves as they travel to the carpal tunnel or injured bone 40 as shown by Figs. 3 and 4.

20 The placement support 22 may be constructed of hard plastics which may be custom molded for a particular patient. The placement support 22 may also be constructed to encapsulate the patient's entire hand/wrist area or to only surround the carpal tunnel or injured or fractured bone areas.

25 With reference to Fig. 5, a block diagram of the ultrasonic transducer assembly circuitry is shown. The transducer assembly circuitry 17 includes a receiver 50 which receives the signals transferred by a signal generator within MOU 12 via cable 36. Receiver 50 is connected to transducer driver 52 which excites transducer 54. The transducer assembly circuitry 17 further includes an internal battery 60 which supplies power to the components within the transducer assembly 16. For example, battery 60 supplies power to signal monitoring circuit 62 and signal driver 66. The signal monitoring circuit 62 provides, preferably, a digital output signal 68 which represents the waveform characteristics of the output
30 of transducer driver 52. These characteristics can be displayed on a digital display and may include, for example, the frequency, pulse repetition frequency, the pulse width and the average output power of the transducer 54. The output signal 68 of signal monitoring circuit 62 is transferred to the signal generator within MOU 12

5 via driver 66 and cable 36. The signal generator may include a processor and a switch for regulating the signal characteristics. Control signals from the MOU 12 are received by receiver 50 via cable 36. Safety or fixture interlock 70, which may include switches on the outer surface of the placement module 14 or transducer assembly 16, ensures that the placement module 14 is properly positioned before
10 providing power to the internal components of the transducer assembly 16.

A second embodiment of the portable ultrasonic treatment apparatus of the present invention is illustrated by Figs. 6-8 and designated generally by numeral 200. The treatment apparatus 200 includes MOU 12 and a series of transducer assemblies 206 on a placement module 208. The transducer assemblies 206 can be placed within pockets 210 of the placement module 208 such that at least one transducer 212 lies over the location of the carpal tunnel 100 or hand/wrist injury. Each transducer 212 is connected to the MOU 12 via wires 214. The circuitry 17 for each transducer assembly 206 may be similar to that disclosed for the first and second embodiments and schematically illustrated by Fig. 5.

20 In operation, the placement module 208 is positioned and firmly secured to the patient's hand or wrist by VELCRO™ tabs 216 as shown by Figs. 7 and 8, such that the transducer assemblies 206 lie over the carpal tunnel 100 or hand/wrist injury. Once the placement module 208 is properly positioned the transducers within the transducer assemblies 206 are excited for a pre-determined period of time to impinge ultrasonic waves to the carpal tunnel 100 or injured bone, 25 as shown by Fig. 8.

30 It is envisioned that the placement module 208 be constructed from suitable conductive plastics, such as conductive ABS plastics with either carbon, stainless steel, nickel or aluminum fibers to forego the use of wires 212 for connecting the transducer assemblies 206 to each other. In such an embodiment, the conductive placement module 208 would be used to electrically connect the transducer assemblies 206 to each other.

5 With reference to Figs. 9 and 10, a third embodiment of the portable ultrasonic treatment apparatus of the present invention is illustrated. In this embodiment, the treatment apparatus 300 includes a MOU (not shown), a placement module 304, ultrasonic transducer assemblies 306, and a pouch (not shown) for providing patient mobility during treatment. The placement module 304 is
10 comprised of a placement band 310 and a placement support 312. The under-side of the placement support 312 includes pockets 314 for placement of transducer assemblies 306 therein. The transducer assemblies 306 may be arranged in a plurality of configurations within pockets 314 such that they lie over the carpal tunnel 100 or location of the hand/wrist injury. Each transducer assembly 306 is
15 connected to the MOU via wires 316. The circuitry 17 for each transducer assembly 306 may be similar to that disclosed for the first and second embodiments and schematically illustrated by Fig. 5.

20 In operation, transducers within transducer assemblies 306 are excited for a pre-determined period of time to impinge ultrasonic waves to the carpal tunnel 100 or injured bone, as shown by Fig. 10.

25 A fourth embodiment of the portable ultrasonic treatment apparatus of the present invention which is primarily suitable for the treatment of carpal tunnel syndrome is illustrated by Figs. 11 and 12. In this embodiment, the apparatus 400 includes at least one ultrasonic transducer 402 positioned on a conductive strip 404 connected to an arm brace 406. The strip 404 is aligned along a patient's carpal tunnel 100 once the arm brace 406 is secured to the patient's arm. The conductive strip 404 is connected via a cable 408 to a MOU (not shown) which contains circuitry for exciting ultrasonic transducer 402 affixed to the conductive strip 404. The conductive strip 404 is preferably constructed from suitable
30 conductive plastics such as conductive ABS plastics with either carbon, stainless steel, nickel or aluminum fibers to forego the use of wires for electrically connecting more than one ultrasonic transducer to the conductive strip 404.

5 In operation, the transducer 402 is excited to impinge ultrasonic waves at the site of the carpal tunnel. It is contemplated that during treatment a gel-like substance is positioned between the transducer 402 and the patient's hand to prevent attenuation of the ultrasonic waves.

10 It will be understood that various modifications can be made to the various embodiments of the present invention herein disclosed without departing from its spirit and scope. For example, various shapes of the pouch and signal generator are contemplated, as well as various types of construction materials. Also, various modifications may be made in the structural configuration of the placement module and the configuration of the components used to excite the 15 ultrasonic transducer. Therefore, the above description should not be construed as limiting the invention but merely as presenting preferred embodiments of the invention. Those skilled in the art will envision other modifications within the scope and spirit of the present invention as defined by the claims presented below.

5

WHAT IS CLAIMED IS:

1. An apparatus for ultrasonically treating carpal tunnel syndrome or hand/wrist injury, comprising:

10 a main operating unit having an internal power source coupled to an ultrasonic transducer assembly, said ultrasonic transducer assembly includes at least one ultrasonic transducer, an ultrasonic signal generator and signal generator circuitry therein; and

15 a placement module configured to receive said transducer assembly such that when said placement module is secured to a patient's hand and/or wrist said at least one ultrasonic transducer is positioned in proximity to the carpal tunnel or site of the hand/wrist injury.

2. The apparatus according to claim 1, wherein said main operating unit is positioned within a pouch worn by the patient to permit portable operation thereof.

20 3. The apparatus according to claim 1, wherein the placement module is configured by connecting at least two placement supports where at least one ultrasonic transducer is secured to at least one placement support.

25 4. The apparatus according to claim 1, wherein the placement module is constructed from a conductive material and said at least one ultrasonic transducer is provided on said placement module is electrically coupled to said main operation unit via said conductive material.

5. The apparatus according to claim 1, wherein the placement module is custom molded for a particular patient.

5 6. A kit for ultrasonically treating carpal tunnel syndrome or hand/wrist
injury while maintaining patient mobility, which comprises:

an ultrasonic transducer assembly having at least one ultrasonic
transducer;

10 a placement module configured to be worn by a patient, said
placement module being configured to receive said transducer assembly such that
when said placement module is worn said at least one ultrasonic transducer is
positioned in proximity to carpal tunnel or site of the hand/wrist injury;

15 an ultrasonic signal generator positioned in said ultrasonic transducer
assembly;

15 a main operating unit; and

16 a pouch configured to receive said main operating unit, said pouch
including a belt so that said pouch can be worn by a patient during treatment
thereby providing patient mobility.

20 7. The kit according to claim 6, wherein said ultrasonic signal generator
includes signal generator circuitry and an internal power source connected to said
signal generator circuitry, a display coupled to said signal generator circuitry to
display treatment sequence data, and said signal generator circuitry including a
processor and means for generating a pulsed RF signal.

25 8. The kit according to claim 6, further comprising safety interlock
means to prevent inadvertent excitation of said at least one ultrasonic transducer.

5 9. An apparatus for ultrasonically treating carpal tunnel syndrome while maintaining patient mobility, comprising:

 at least one ultrasonic transducer;

 a strip configured to receive said at least one ultrasonic transducer and for placement along patient's carpal tunnel; and

10 a main operating unit having an internal power source coupled to an ultrasonic assembly, said ultrasonic transducer assembly includes an ultrasonic single generator and signal generator circuitry therein, said ultrasonic transducer assembly coupled to said at least one ultrasonic transducer.

15 10. An apparatus according to claim 9, wherein said signal generator circuitry including a processor, means for generating a pulsed signal, and a switch coupled to said processor for regulating said pulsed signal.

11. The apparatus according to claim 9, wherein said main operating unit is positioned within a pouch worn by the patient to permit portable operation thereof.

20 12. A method for ultrasonically treating carpal tunnel syndrome or a hand/wrist injury, comprising the following steps:

 providing a main operating unit having an internal power source coupled to an ultrasonic transducer assembly, said ultrasonic transducer assembly includes at least one ultrasonic transducer, an ultrasonic signal generator and signal generator circuitry therein;

25 providing a placement module configured to receive said transducer assembly such that when said placement module is secured to a patient's hand and/or wrist said at least one ultrasonic transducer is positioned in proximity to the carpal tunnel or site of the hand/wrist injury; and

5 exciting said at least one ultrasonic transducer to impinge ultrasonic waves at or near the carpal tunnel or site of the hand/wrist injury.

13. A method for ultrasonically treating carpal tunnel syndrome while maintaining patient mobility, comprising the following steps:

10 releasably securing at least one ultrasonic transducer coupled to a signal generator to a strip;

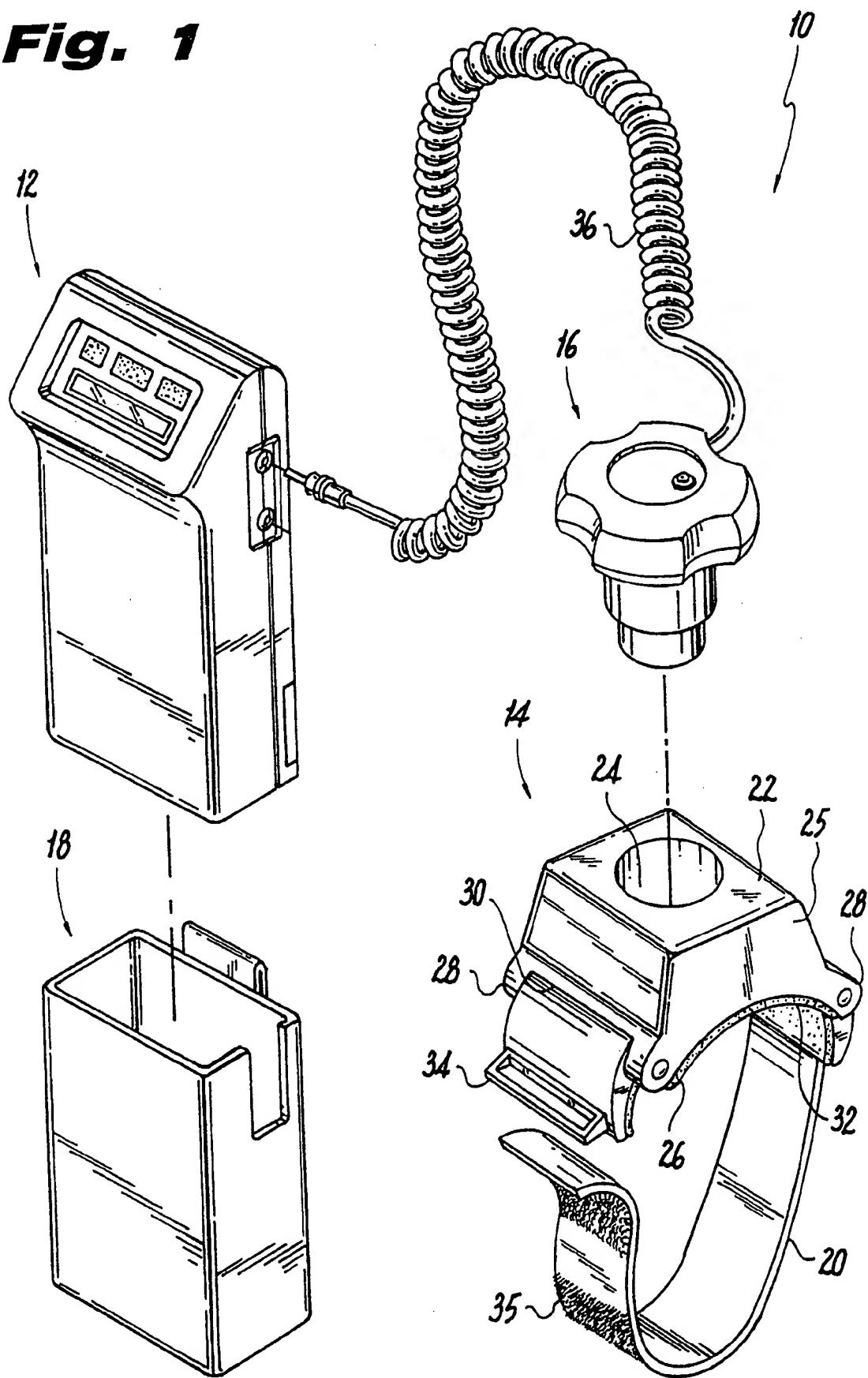
affixing said strip on a patient's hand and/or wrist, such that said at least one transducer is in proximity to the carpal tunnel; and exciting said at least one ultrasonic transducer by actuating said signal generator to impinge ultrasonic waves to the carpal tunnel.

14. A method according to claim 13, further including the step of:

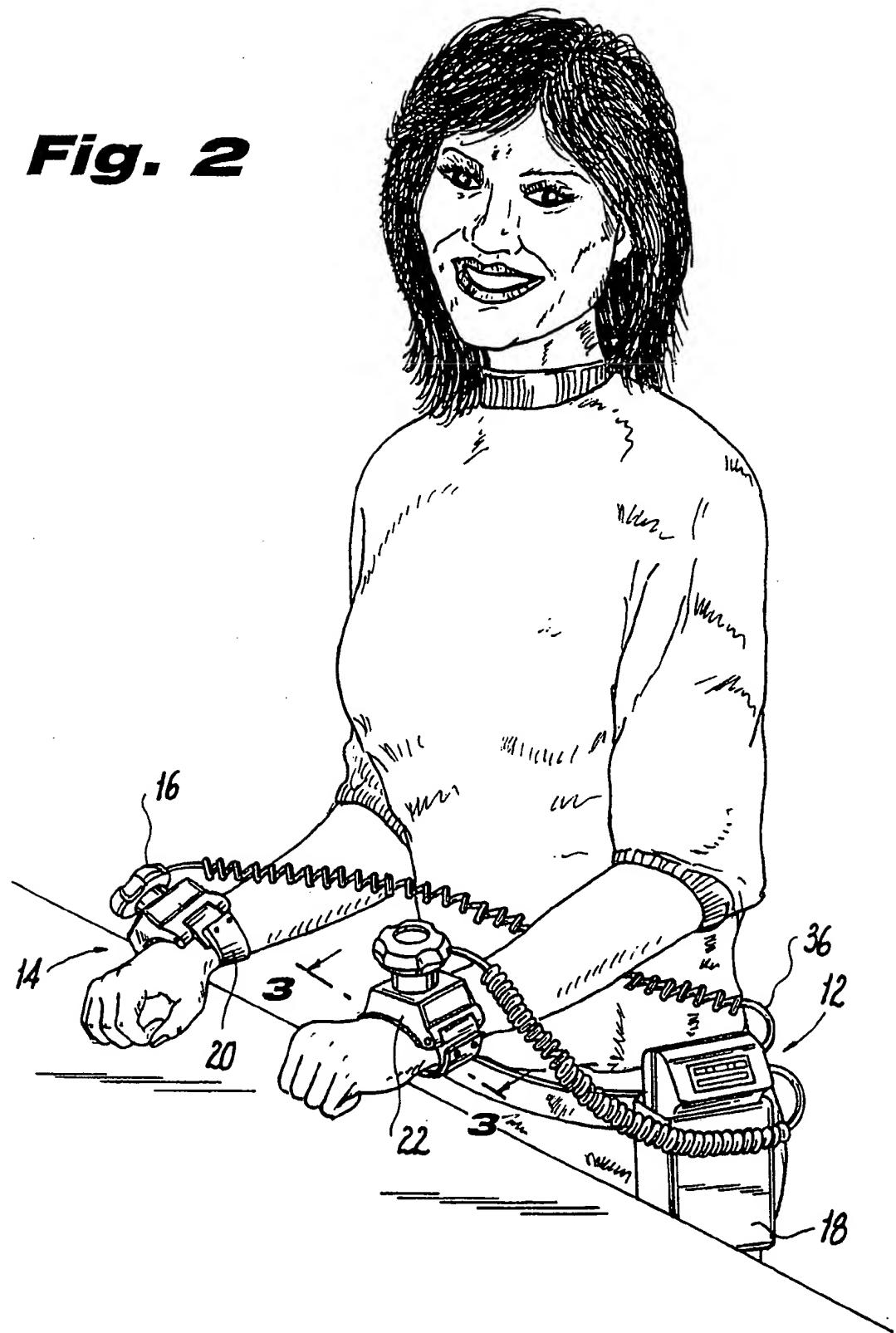
connecting said at least one ultrasonic transducer to an operating unit, said operating unit having an internal power source for permitting patient mobility during treatment.

15. A method according to claim 14, further including the step of:

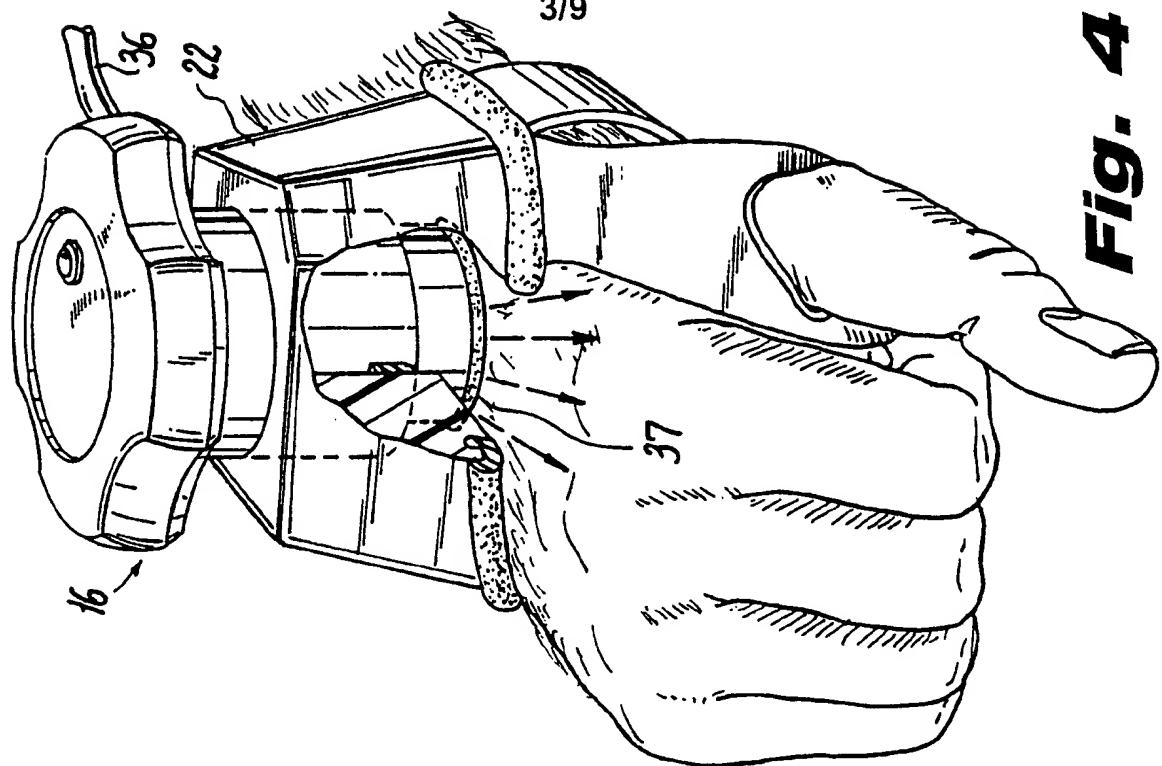
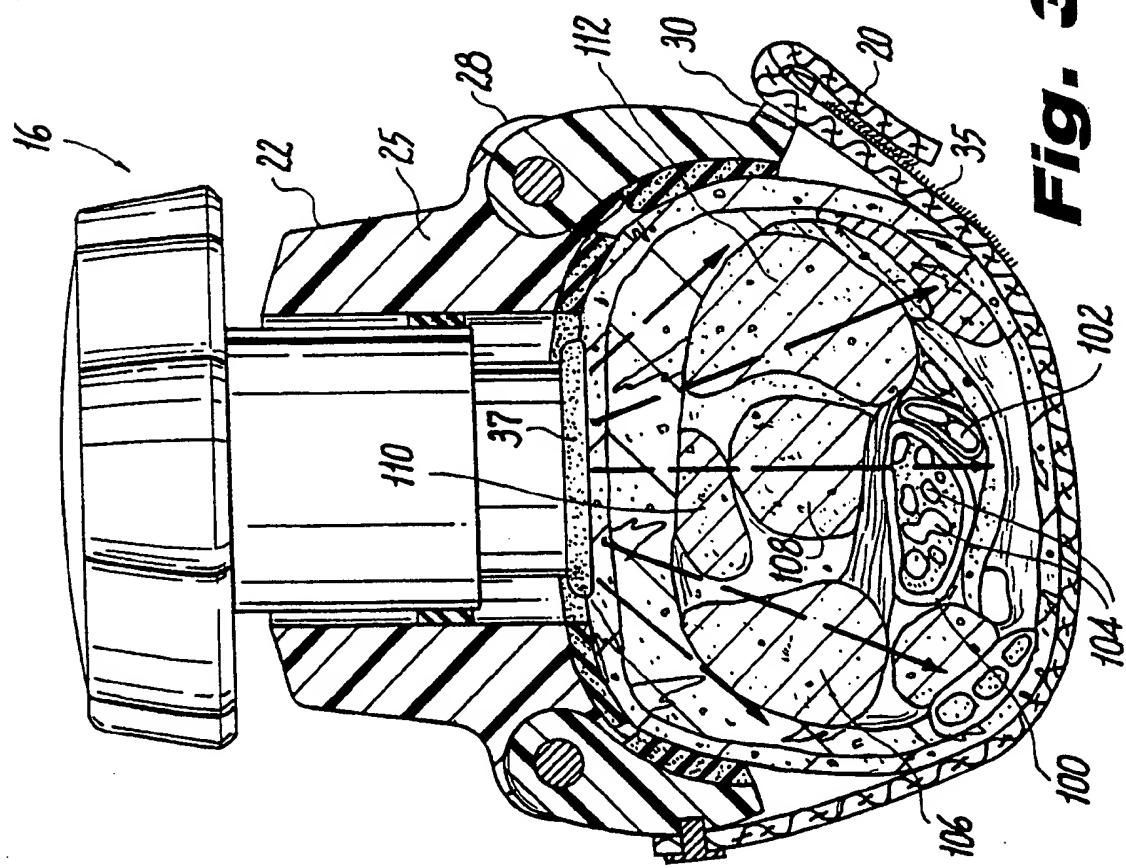
20 placing a gel-like substance between the at least one transducer and
the patient's hand and/or wrist to minimize attenuation of said ultrasonic waves.

Fig. 1

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Fig. 2

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**Fig. 4****Fig. 3**

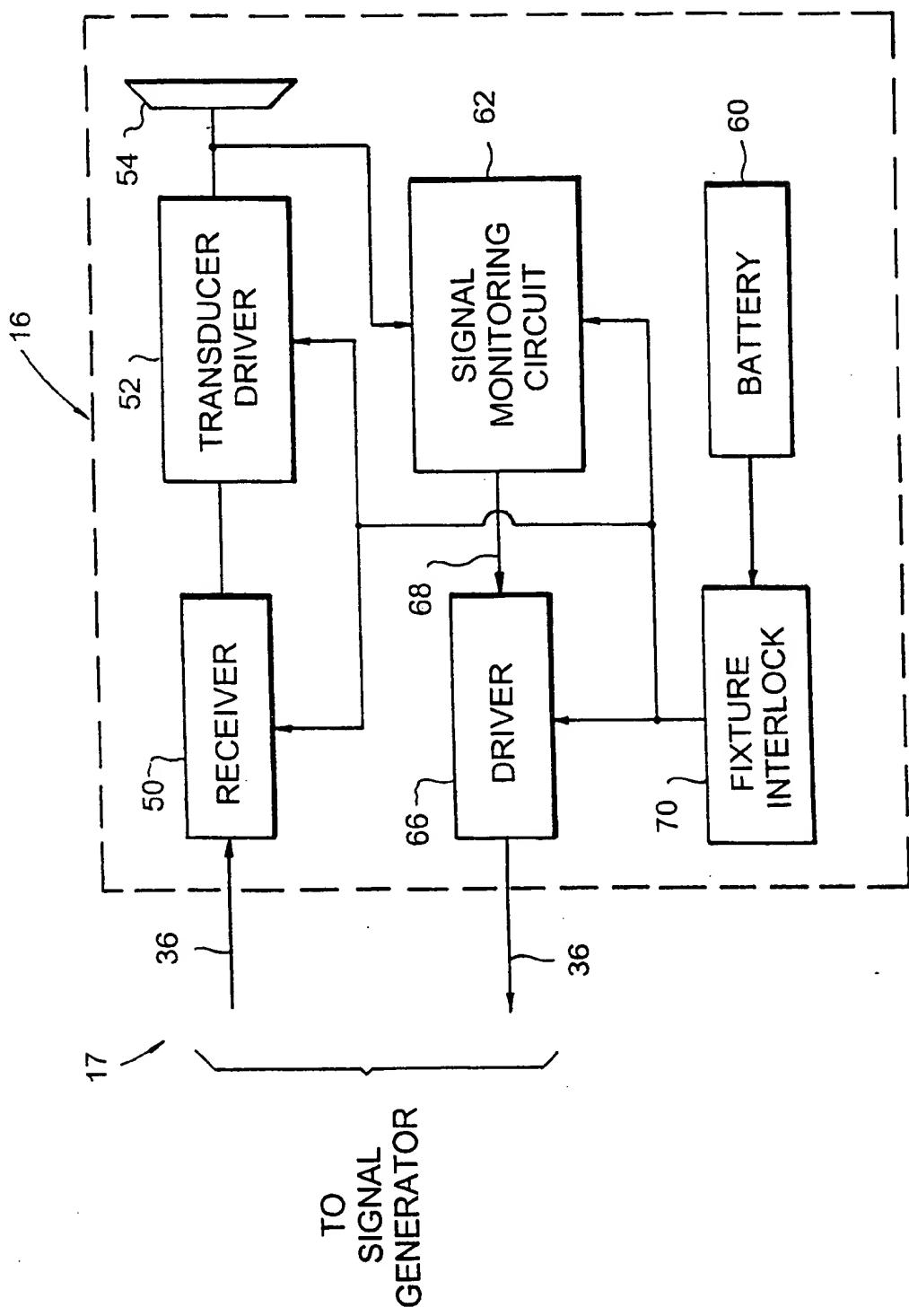


Fig. 5

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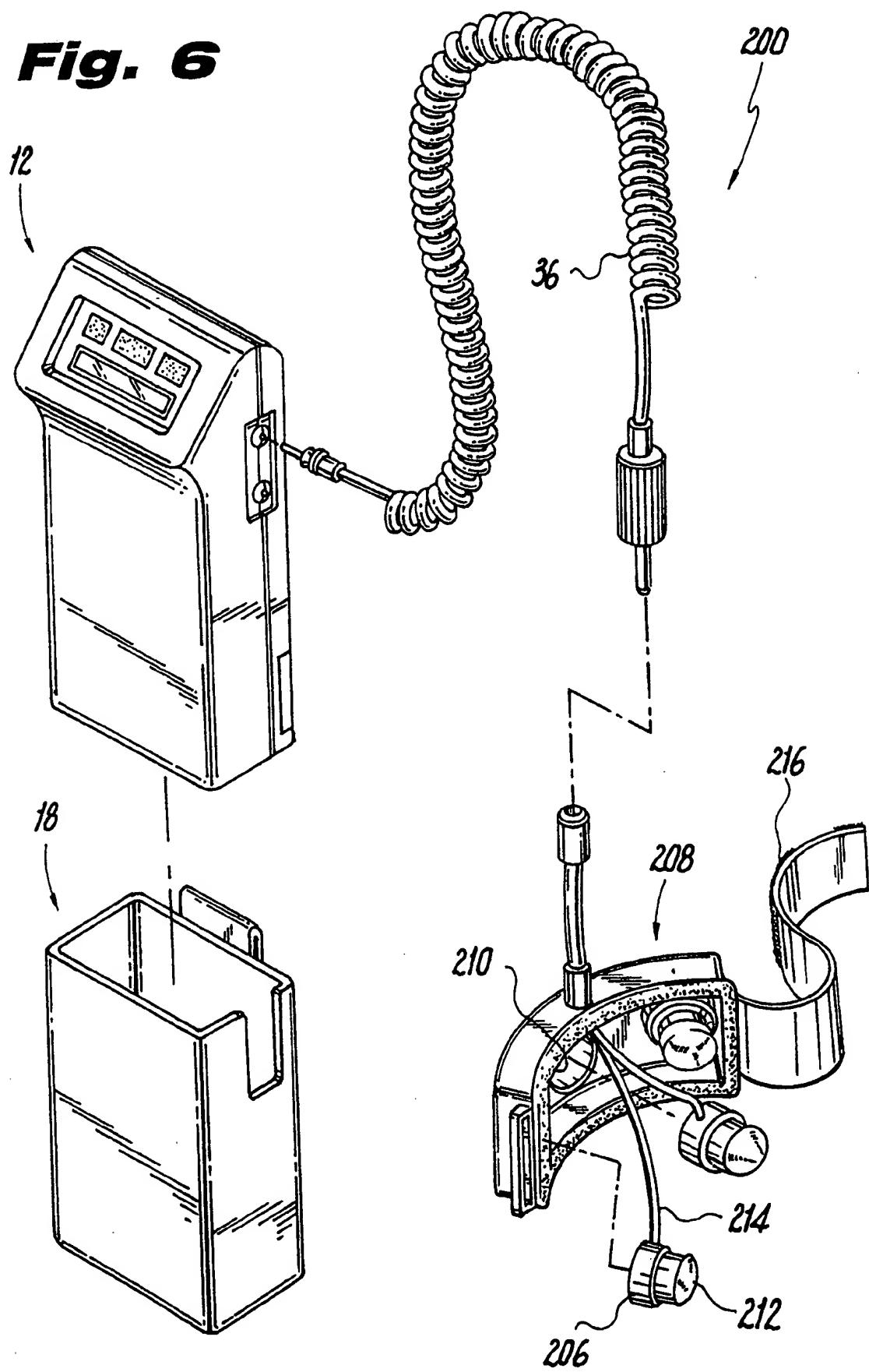
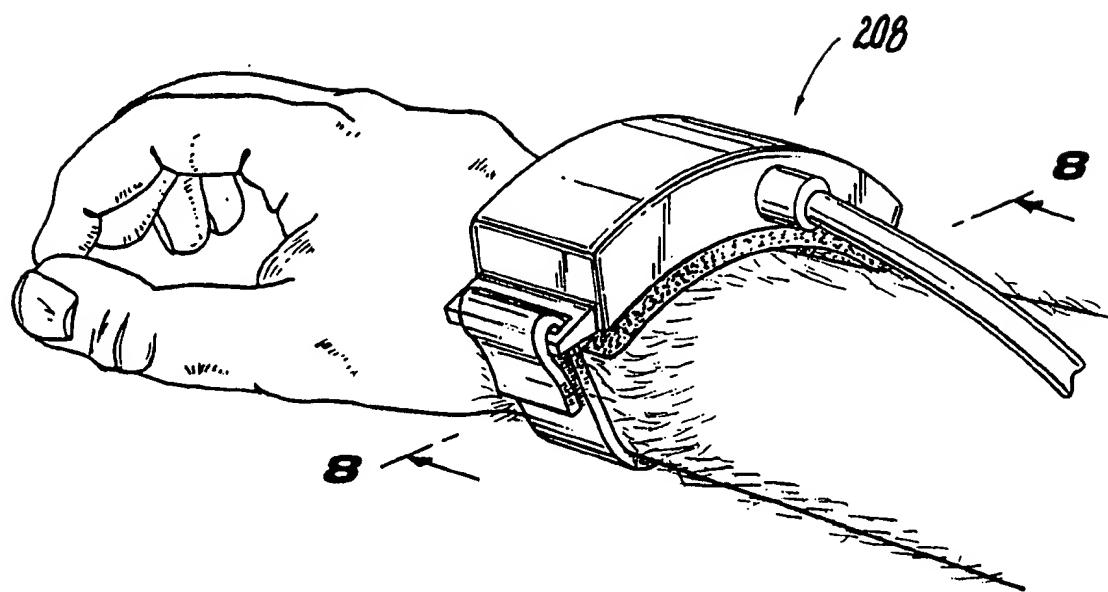
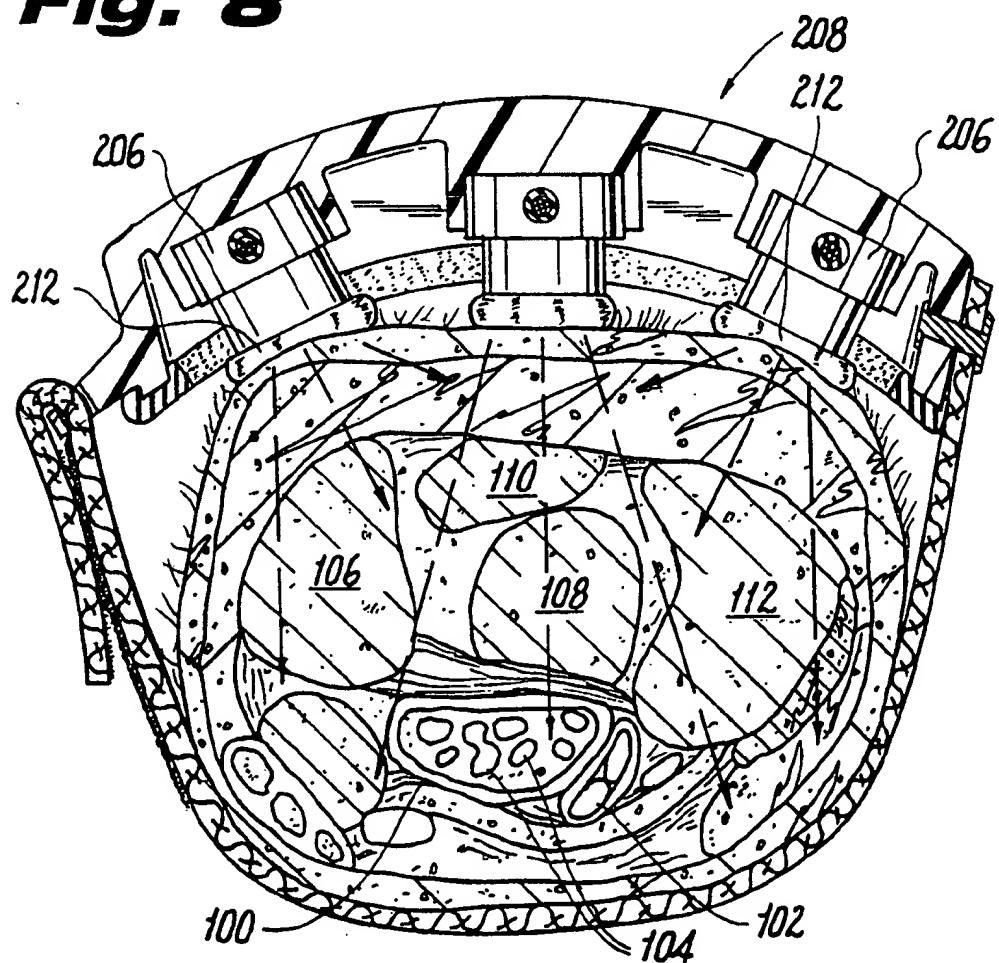
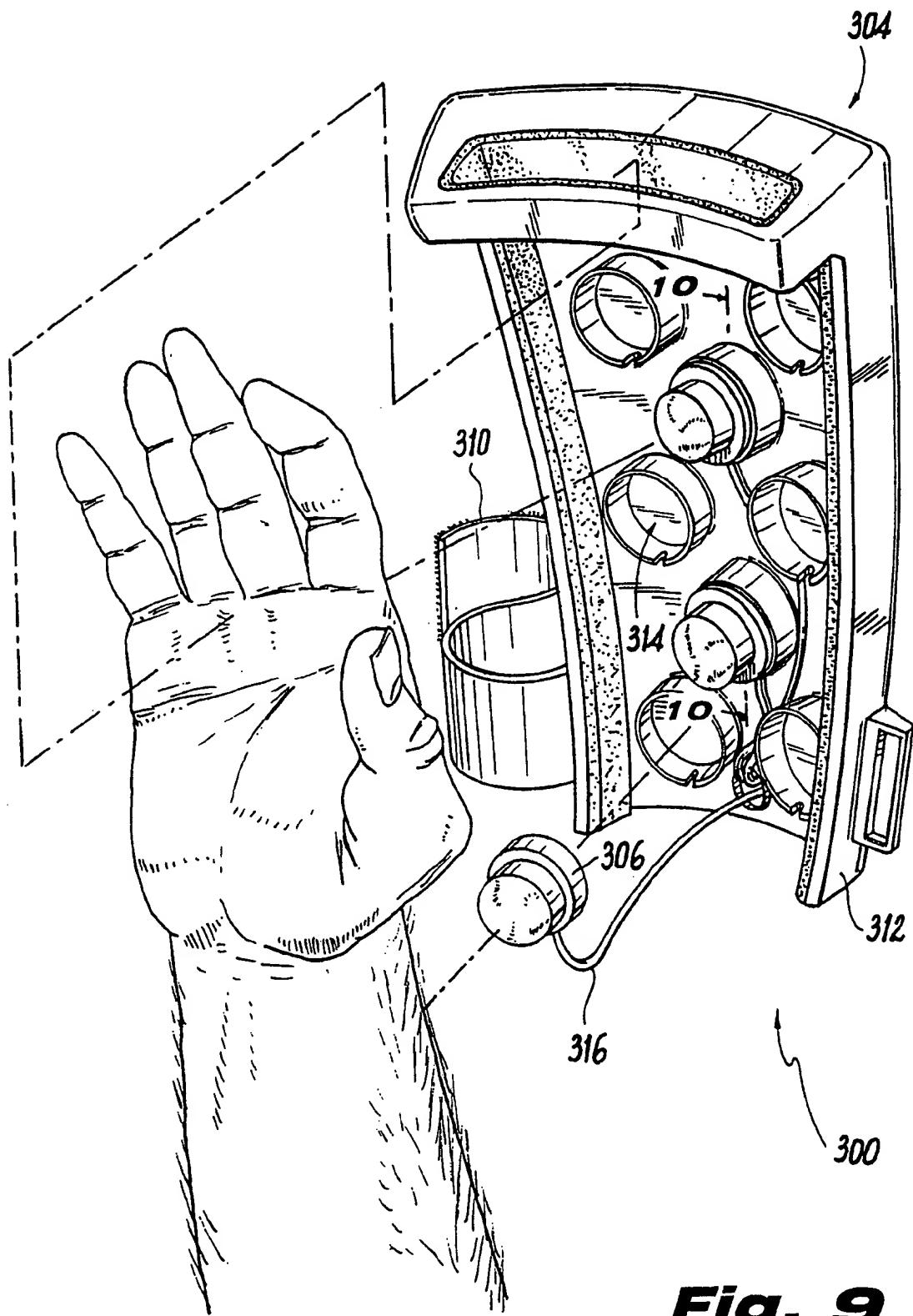
Fig. 6

Fig. 7

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**Fig. 8**

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**Fig. 9**

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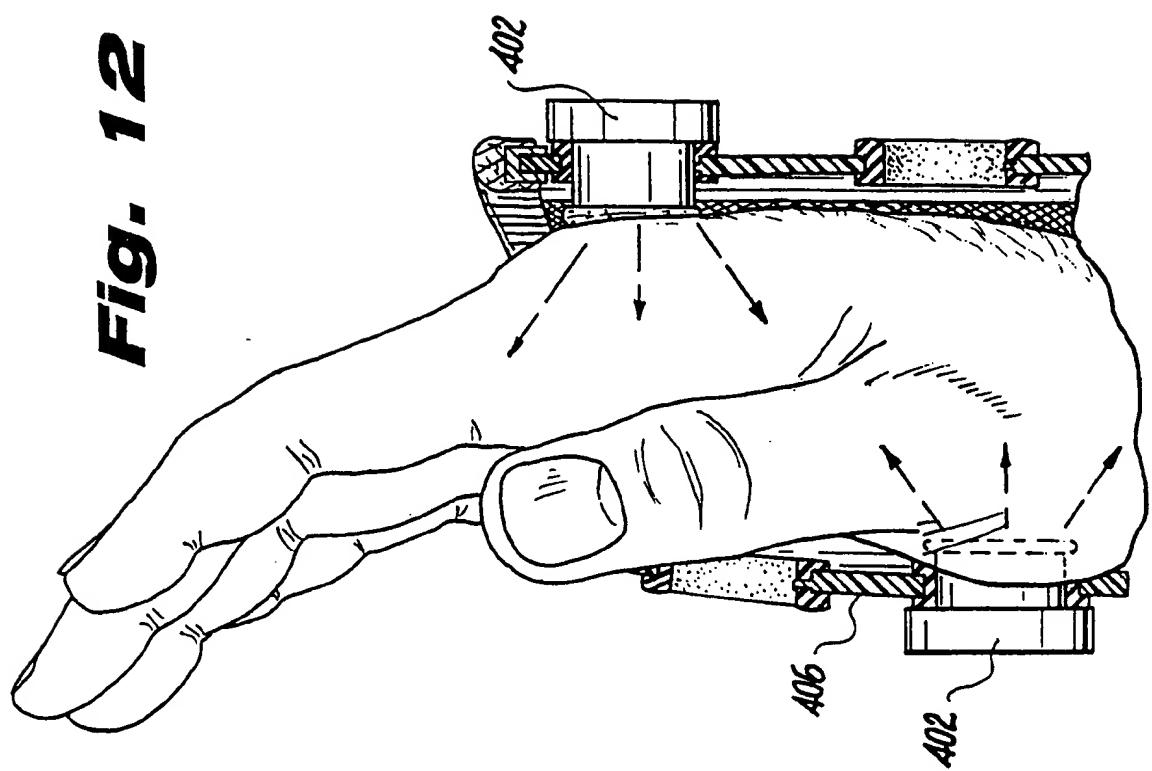
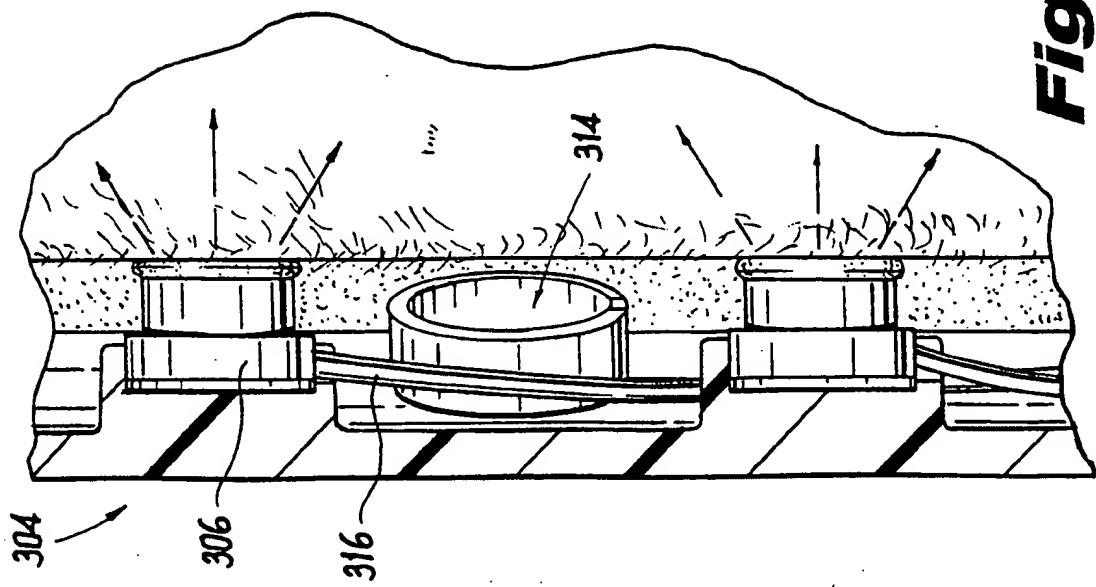
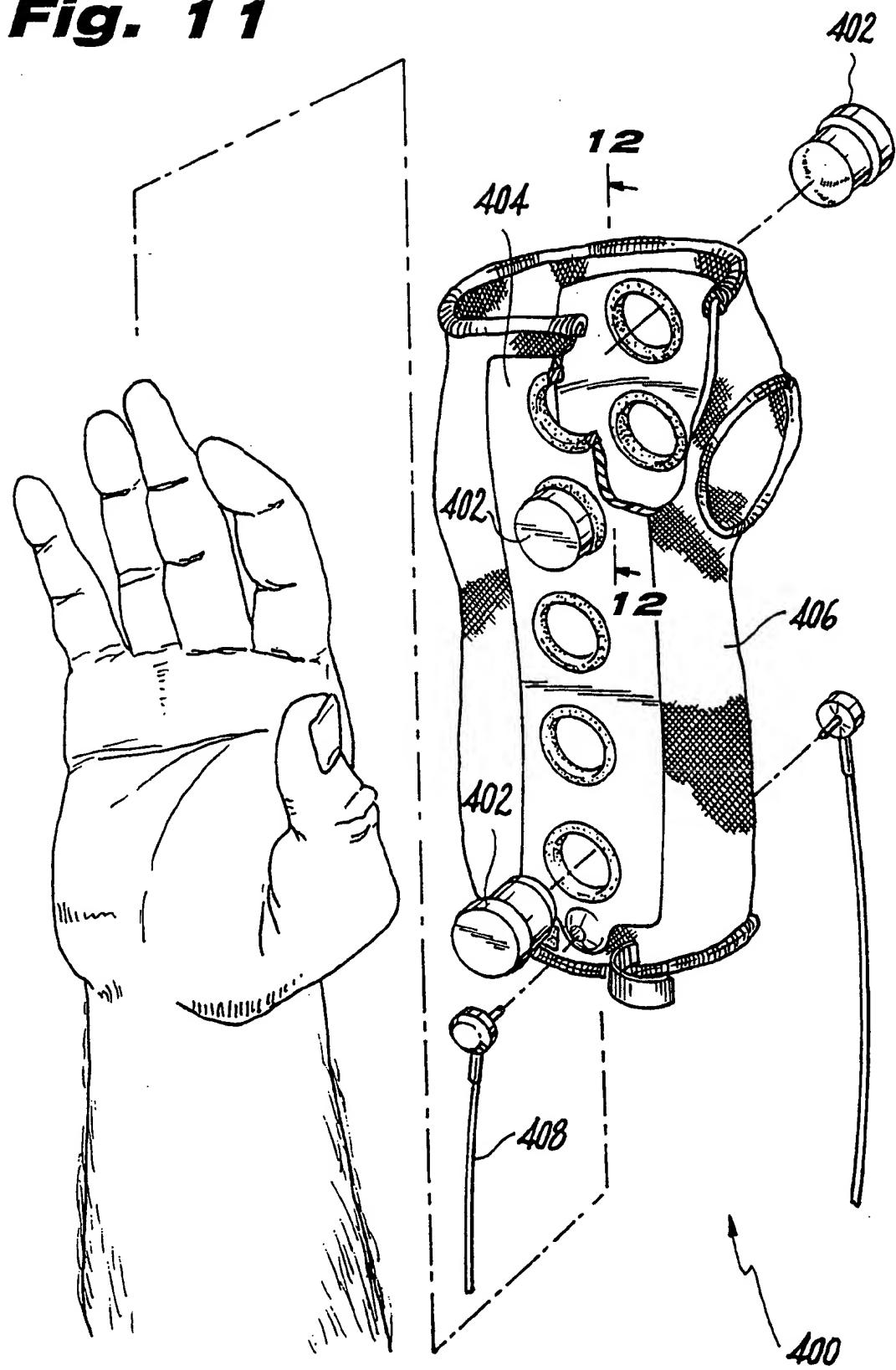
Fig. 12**Fig. 10**

Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/21341

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) A61B 17/56

US CL 601/002

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 601/002, 003, 004; 600/437, 439; 604/22

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,556,372 A (TALISH et al.) 17 September 1996, see entire document.	1-12
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Y		13-15
A, P	US 5,730,705 A (TALISH et al.) 24 March 1998.	1-15
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Further documents are listed in the continuation of Box C.

See patent family annex.

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Date of the actual completion of the international search

30 NOVEMBER 1998

Date of mailing of the international search report

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